UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PFIZER INC.

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue SW
Washington, DC 20201;

AND

ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services,
200 Independence Avenue SW
Washington, DC 20201;

AND

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL,
330 Independence Avenue SW
Washington, DC 20201;

AND

CHRISTI A. GRIMM, in her official capacity as Principal Deputy Inspector General of and Senior Official in the U.S. Department of Health and Human Services Office of Inspector General,
330 Independence Avenue SW
Washington, DC 20201,

Defendants.

Case: _____

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Pfizer Inc. ("Pfizer") seeks a declaratory judgment against Defendants the United States Department of Health and Human Services ("HHS"), Alex M. Azar II in his capacity as the Secretary of HHS, the HHS Office of Inspector General ("OIG"), and Christi A. Grimm in her

capacity as the Principal Deputy Inspector General of and Senior Official in OIG, and in support thereof, states as follows:

INTRODUCTION

1. Pfizer brings this declaratory judgment action to enable it to provide financial assistance to Medicare beneficiaries who are otherwise unable to afford Vyndaqel® (tafamidis meglumine) or Vyndamax™ (tafamidis) (collectively, "tafamidis" or the "Medications")—two important medical advances and the only pharmacological treatments approved by the U.S. Food and Drug Administration ("FDA") for a rare and fatal heart condition called Transthyretin Amyloid Cardiomyopathy ("ATTR-CM"). Without this Court's intervention, Pfizer is unable to provide this financial assistance because of the significant risk of a criminal or other government enforcement action arising from erroneous legal restrictions imposed by OIG. As a consequence, without relief from this Court, Medicare beneficiaries who are unable to afford copay obligations under the Medicare Part D prescription drug benefit will continue to be denied access to their Medicare benefits and these life-changing medical breakthroughs.

2. The governmental restrictions that are denying patients access to their prescribed medications are a direct result of a series of actions by OIG that, in combination, prevent pharmaceutical manufacturers from providing copay assistance to Medicare Part D beneficiaries, including in the circumstances of Pfizer's proposed programs, on the theory that such assistance constitutes an unlawful kickback. Accordingly, before providing financial assistance to Medicare Part D beneficiaries who cannot afford the out-of-pocket costs of tafamidis, Pfizer is forced to seek a declaratory judgment from this Court that its proposed programs do not violate federal anti-kickback laws.

3. ATTR-CM is a rare medical condition affecting the heart muscle, causing the heart to stiffen and thereby limiting its ability to pump blood to the body. Patients with ATTR-CM experience a progressive decline in function, beginning with fatigue and shortness of breath and ending with potential heart failure, inability to perform even the most basic daily activities, and eventually death. ATTR-CM disproportionately affects individuals over the age of 60 and, in the United States, the hereditary form of the disease primarily afflicts African-American men. No cure exists for ATTR-CM, and, prior to the availability of tafamidis, life expectancy typically was only 2 – 3.5 years from the time of diagnosis. The precise number of people who suffer from ATTR-CM is unknown because the disease historically has been underdiagnosed, but Pfizer estimates the prevalence to be approximately 100,000 – 150,000 patients in the United States based on the best available peer-reviewed literature. FDA confirmed that ATTR-CM is a rare disease under the Orphan Drug Act, a federal statute passed to encourage the development of treatments for such rare conditions.[1]

4. The Medications are the first and only FDA-approved pharmacological treatments for ATTR-CM. Tafamidis was developed after more than a decade of scientific research—including extensive bench testing, animal studies, and clinical trials—and has been shown to significantly reduce mortality, decrease cardiovascular related hospitalizations, and slow the decline in quality of life for people suffering with ATTR-CM. Its approval is a major medical advance that offers real hope to patients suffering with this devastating condition.

[1] Pub. L. No. 97-414, § 1, 96 Stat. 2049 (1983) (codified at 21 U.S.C. § 360bb(a)(2)). The Orphan Drug Act defines a "rare disease or condition" as one "which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug." 21 U.S.C. § 360bb(a)(2).

5. The Medications have a list price of $225,000 for a one-year course of treatment, which is well below comparable novel therapies approved to treat other rare diseases. That price, moreover, is consistent with the Medications' strong efficacy and safety profile, its slowing of the decline in functional status and quality of life, and the relatively small population of patients with ATTR-CM. The Medications also cost substantially less than a dual heart and liver transplant, which is the other potential treatment option for patients with ATTR-CM.

6. Due to the age of the affected population, most ATTR-CM patients are Medicare beneficiaries. Most Medicare plans provide full coverage for tafamidis at the list price, provided prior authorization criteria are met. However, under the standard Medicare Part D benefit structure, a patient must pay significant out-of-pocket costs for tafamidis—approximately $13,000 annually. These costs are prohibitively expensive for many patients. But, because Part D has no cap on beneficiaries' out-of-pocket costs, and because patients are responsible for a coinsurance or percentage of the cost, a reduction in tafamidis' list price—even by half—would not enable many patients to afford the out-of-pocket costs. The result is that tafamidis is only affordable to those patients wealthy enough to pay the out-of-pocket costs or those with incomes so low that Medicare waives most of the out-of-pocket costs under the Low Income Subsidy program. The crux of this action is the legality of Pfizer's efforts to help ATTR-CM patients caught between those financial extremes, who cannot afford to fill their doctor's prescription for the Medications even though they would benefit from these breakthrough treatments.

7. Pfizer is committed to helping ensure that all patients suffering from ATTR-CM can afford these breakthrough Medications. To address that need, Pfizer currently makes the Medications available for free to all ATTR-CM patients—including those on Medicare—who are prescribed the Medications and have annual income up to 500% of the Federal Poverty Level (i.e.,

$86,200 for a family of two in 2020). However, there remain many Medicare patients with incomes above this level who have been prescribed the Medications but are unable to afford the copay and coinsurance requirements of Medicare Part D. Therefore, Pfizer proposes to implement copay assistance programs for middle-income Medicare patients with demonstrated financial need who do not qualify for the other available assistance options. Pfizer already offers a similar program for commercially insured patients, without regard to financial need.

8. These proposed Medicare programs—collectively referred to as "Proposed Copay Assistance Programs" or "Programs"—include (1) directly providing copay and coinsurance assistance to Medicare patients through a copay card or coupon (the "Direct Copay Assistance Program") and (2) funding an existing independent charity that would provide copay assistance to Medicare patients diagnosed with ATTR-CM who require financial support to access tafamidis as well as any other prescription drugs used to treat the symptoms of the disease and any potential side effects of its treatment (the "Independent Charity Program").

9. As detailed below, Pfizer's proposed Programs do not violate federal statutes—specifically the Anti-Kickback Statute, *see* Social Security Act, §§ 1128(b)(7) and 1128A(a)(7), ("AKS") and the Beneficiary Inducement Statute, *see id.* § 1128A(a)(5), ("BIS")—that prohibit kickbacks made with the intent to corrupt medical decision making at the expense of federal health care programs. Rather, the proposed Programs are designed to ensure that financial obstacles do not prevent patients from accessing these breakthrough treatments *after* a physician has objectively determined that a patient has ATTR-CM and prescribed the only FDA approved medications for this terminal disease. Under such circumstances, the Programs do not constitute an illegal kickback.

10. However, as the result of a series of actions by OIG, Pfizer is unable to implement its proposed Programs to assist ATTR-CM patients. Together, these actions establish OIG's position that the AKS and the BIS prohibit pharmaceutical manufacturers (but not others) from providing financial assistance to help Medicare patients cover their out-of-pocket costs, irrespective of the circumstances. OIG has further limited aid to patients by construing the AKS and BIS to impose strict restrictions on pharmaceutical manufacturers' ability to fund and communicate with independent charities that provide financial assistance to Medicare patients. Meanwhile, OIG, in conjunction with the U.S. Department of Justice ("DOJ"), has taken aggressive steps to enforce OIG's strict construction of the AKS and BIS in enforcement actions against pharmaceutical manufacturers who have provided copay assistance or contributed to independent charities that provided financial assistance to Medicare patients. As a result, without a declaration from this Court, Pfizer is prevented from taking action inconsistent with OIG's construction of these statutes.

11. Pfizer supports OIG's mission to enforce the AKS and the BIS to prevent fraud and abuse in the health care system, and nothing in this Complaint should be viewed as an effort to undermine that important goal. But Pfizer disagrees with OIG that the AKS and BIS properly can be construed to prohibit copay assistance when, as in the circumstances of the proposed Programs, the copay assistance does not constitute "remuneration" and is not intended to influence prescriptions for the Medications in the kind of corrupt or improper way addressed by those statutes. For the past year, Pfizer has engaged with OIG through a formal advisory opinion process to obtain OIG's acknowledgement that Pfizer's proposed Programs fall outside the proscriptions of the AKS and BIS, and to obtain OIG's guidance on how the Programs might be modified to address any concerns the agency might have. OIG has refused, however, to acknowledge that

Pfizer's proposed Programs are legal under the AKS and BIS, or to suggest proposed modifications. As a result of OIG's rejection of Pfizer's request and the agency's prior guidance prohibiting pharmaceutical manufacturers from providing copay assistance to Medicare beneficiaries, Pfizer faces significant risks of criminal or other enforcement action if it proceeds with these Programs. Where, as here, Pfizer respectfully disagrees with OIG's conclusion that its proposed Programs would violate those statutes, it is left with no alternative but to seek judicial relief. Pfizer and the very sick patients who will be denied these critical Medications are out of alternatives.

12. In addition, significant First Amendment concerns would be raised if the AKS and BIS were construed, as OIG does, to restrict pharmaceutical manufacturers' communications with and donations to independent charities that provide financial assistance to Medicare patients. OIG's construction burdens Pfizer's established rights to participate in a charitable endeavor and engage in expressive giving in support of patients suffering from ATTR-CM, and improperly singles out pharmaceutical manufacturers for special restrictions on this type of charitable giving. OIG's position, which prohibits certain communications with independent charities concerning financial assistance, is not narrowly tailored to a compelling government interest in combatting fraud or abuse, and therefore violates the First Amendment's Free Speech guarantee.

13. OIG's position on copay assistance leads to perverse and unequal results depending on a Medicare beneficiary's economic status. Under OIG's position, Medicare provides insurance benefits for the Medications for the wealthiest and the poorest Medicare ATTR-CM patients, but effectively denies this same insurance benefit to similarly situated middle-income patients. The wealthiest enrollees can afford tafamidis' out-of-pocket costs; the poorest enrollees will have their out-of-pocket obligations satisfied by Medicare's Low Income Subsidy. For each of these

groups—the wealthiest and the poorest—Medicare pays the remaining share of the Medication's costs. But middle-income Medicare ATTR-CM patients who cannot afford the copay and coinsurance for the Medications forgo filling their prescriptions, and Medicare pays nothing. OIG takes the view that any manufacturer who helps *those* middle-income patients with their out-of-pocket costs has committed health care fraud and may be subject to prosecution or other enforcement action under the AKS and BIS. That interpretation effectively bars middle-income Medicare recipients from accessing their federal health care insurance benefits based solely on their economic status. Such a fundamentally irrational application of the Medicare Part D benefit scheme would violate the equal protection principles enshrined in the Fifth Amendment's Due Process Clause. The AKS and BIS should be interpreted to avoid these constitutional concerns.

14. Accordingly, Pfizer requests a declaration that the Proposed Copay Assistance Programs do not violate the AKS or the BIS.

THE PARTIES

15. Plaintiff Pfizer Inc. is a research-based biopharmaceutical company that develops and manufactures medicines for patients across the globe. Pfizer strives to develop breakthrough therapies that change people's lives, with a focus on internal medicine, inflammation and immunology, oncology, rare diseases, vaccines, sterile injectables, and anti-infectives. Pfizer devotes billions of dollars annually to research in these areas and has developed numerous breakthrough treatments. Pfizer is committed to funding programs that provide public benefit, advance medical care, and improve patient outcomes. To this end, Pfizer collaborates with health care providers, governments, and local communities to support and expand access to reliable, affordable health care. Pfizer is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York 10017.

16. Defendant United States Department of Health and Human Services ("HHS") is an executive department of the United States. HHS oversees multiple health care-related agencies including the Centers for Medicare & Medicaid Services ("CMS"). HHS's headquarters are in Washington, D.C.

17. Defendant United States Department of Health and Human Services Office of Inspector General ("OIG") is an office within HHS that was established in 1976. OIG oversees aspects of the Medicare and Medicaid programs, including through efforts to promote efficiency and economy in departmental operations and to identify and eliminate fraud, abuse, and waste in those programs. The Secretary of HHS has delegated to OIG authority to exclude individuals and entities from participation in federal health care programs, prohibiting payment for any product or service the excluded entity or individual furnishes. The Health Care Fraud and Abuse Control Program, established by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), authorizes OIG to provide guidance to the health care industry about potential problems or areas of special interest. OIG's headquarters are in Washington, D.C.

18. Defendant Alex M. Azar II is sued in his official capacity as Secretary of HHS, the most senior official in the department. Under section 1128 of the Social Security Act, as Secretary of HHS, Secretary Azar has direct authority to exclude from participation in federal health care programs any individual or entity convicted of certain offenses or deemed by the Secretary to have engaged in certain improper conduct. Secretary Azar directly supervises the Inspector General and is thus responsible for any guidance that OIG issues as well as OIG's statutory and regulatory enforcement activities.

19. Defendant Christi A. Grimm is sued in her official capacity as Principal Deputy Inspector General of and senior official in OIG. As Principal Deputy Inspector General, Ms.

Grimm is the senior official at OIG and is responsible for its oversight, guidance, rule-making process, and enforcement activities, including its delegated exclusion authority.

JURISDICTION AND VENUE

20. Pfizer brings this action pursuant to the First and Fifth Amendments to the United States Constitution, the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and the Administrative Procedure Act, 5 U.S.C. § 702.

21. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1361 because Pfizer's causes of action arise under the United States Constitution and laws of the United States.

22. Venue is proper pursuant to 28 U.S.C. § 1391(e) because Pfizer's principal place of business is in this judicial district.

23. There is currently an actual, justiciable controversy between the parties regarding whether Pfizer may, consistent with the AKS and BIS, provide assistance to middle-income Medicare Part D beneficiaries to help them access Pfizer's breakthrough ATTR-CM therapies.

24. Declaratory relief will resolve this controversy and eliminate the chill that the government's interpretation of the statutes and regulations currently has on Pfizer's ability to provide copay assistance.

PFIZER PROPOSES TO PROVIDE FINANCIAL ASSISTANCE TO ALLOW MEDICARE PART D BENEFICIARIES TO ACCESS ITS BREAKTHROUGH THERAPIES FOR A FATAL CARDIAC CONDITION

I. Transthyretin Amyloid Cardiomyopathy ("ATTR-CM") and its Patient Population

25. ATTR-CM is a rare, progressive cardiac condition characterized by deposits of amyloid protein in the heart muscle. Left untreated, a patient with ATTR-CM may suffer progressive heart failure, including severe shortness of breath and limitations on physical activity, which may end in death. In the latter stages of the disease, patients may have difficulty performing even the most basic activities of daily living and frequently require full-time care. Prior to the

availability of tafamidis, patients with ATTR-CM had a median life expectancy of 2 – 3.5 years from diagnosis.

26. Diagnosis of ATTR-CM is made objectively by heart biopsy or nuclear scintigraphy (an imaging technology).

27. The precise number of people who suffer from ATTR-CM is unknown. It is estimated that approximately 100,000 – 150,000 Americans may have the disease, which disproportionately affects the elderly. Most ATTR-CM patients are Medicare beneficiaries and many have limited financial resources.

II. Pfizer's Development of Tafamidis to Treat ATTR-CM

28. Tafamidis is the result of nearly two decades of research and testing. While not a cure, tafamidis offers ATTR-CM patients hope for a longer and better life and may provide a bridge to future therapies.

29. Before development of tafamidis, no FDA-approved pharmacological treatments existed for ATTR-CM. A small number of ATTR-CM patients have undergone dual heart and liver transplants, in hopes of curing the disease, or at least improving their prognosis. These procedures have had some success, but limited application in practice, because most patients with ATTR-CM are too sick and have too many other medical problems to meet transplant criteria. Furthermore, the total cost of an individual patient's transplants can exceed $2 million.

30. The tafamidis molecule first was developed in the early 2000s. Over the next decade, extensive laboratory, pre-clinical, and clinical studies evaluated both the safety and efficacy of the molecule. As with other investigational medicines for rare diseases, these studies were undertaken even though, at the outset, the likelihood of success was very low.

31. Substantial research and development time and costs are required to develop novel therapies like tafamidis. The development of medicines for rare diseases, like ATTR-CM, is

complicated by the fact that the diseases typically are not well characterized or understood, appropriate efficacy endpoints are not defined, and patient populations are very small.

32. These unique challenges make development of medicines for rare diseases even more difficult and expensive. As a consequence of these hurdles, the cost of developing medicines for rare (and other) diseases has continued to rise. As the Office of Health Economics, a British research entity, observed in 2012, biopharmaceutical companies' out-of-pocket drug development expenditures have risen by 600% since the 1970s, while success rates for bringing these developments to market have fallen, making it more expensive than ever for manufacturers to develop rare disease medications.[2]

III. Pfizer's Successful Clinical Trials Demonstrate Tafamidis' Safety and Efficacy in Extending Life for ATTR-CM Patients

33. Pfizer acquired rights to the tafamidis molecule in 2010. In 2012, FDA granted Pfizer orphan drug designation for the development of tafamidis as a treatment for ATTR-CM. Orphan drug designation is a special status FDA may grant to drugs that treat a rare disease, where both the drug and the disease meet certain regulatory and statutory criteria specified in the Orphan Drug Act, 21 U.S.C. § 360bb, and FDA's implementing regulations, 21 CFR Part 316. Orphan designation qualifies the sponsor of the drug for various development incentives designed to encourage innovation of treatments for rare diseases.

34. In 2013, Pfizer began enrollment in the landmark Transthyretin Amyloid Cardiomyopathy Clinical Trial ("ATTR-ACT"), which was an international, multicenter, double-blind, placebo-controlled, randomized clinical trial designed to evaluate the efficacy and safety of tafamidis in patients with hereditary and wild-type ATTR-CM. ATTR-ACT was the largest

[2] Jorge Mestre-Ferrandiz et al., Office of Health Economics, *The R&D Costs of a New Medicine* (Dec. 2012), https://www.ohe.org/publications/rd-cost-new-medicine#.

multicenter investigation of a treatment for ATTR-CM ever conducted, and it was completed after approximately six years in February 2018.

35. The study was sponsored by Pfizer and conducted by leading researchers at some of the most prominent medical institutions in the world, including Columbia University, the Mayo Clinic, Stanford University, the Cleveland Clinic, University College London and St. Bartholomew's Hospital, London, and the French Referral Center for Cardiac Amyloidosis.

36. The study demonstrated tafamidis' value as a breakthrough therapy that changes the lives of patients with ATTR-CM, who until now had no approved medicines for this rare, debilitating, and fatal disease.

37. As reported in the September 13, 2018, issue of the *New England Journal of Medicine,* the combination of all-cause mortality and cardiovascular-related hospitalizations (the primary endpoint of the study) was significantly lower among patients who received tafamidis than among those who received placebo: patients treated with tafamidis had a 30% lower all-cause mortality rate and experienced 32% fewer cardiovascular-related hospitalizations than those taking placebo. At the end of the trial, 70% of tafamidis patients were alive, compared to only 57% of those receiving placebo.

38. More recent data demonstrates tafamidis' immense value to public health. For example, extrapolation of data from the ATTR-ACT study indicates an approximately 18-month increase in median overall survival for patients treated with tafamidis as compared to those receiving placebo.[3]

[3] *See* Benjamin Li *et. al*, *Extrapolation of Survival Benefits in Patients with Transthyretin Amyloid Cardiomyopathy Receiving Tafamidis: Analysis of the Tafamidis in Transthyretin Cardiomyopathy Clinical Trial*. Cardiology and Therapy (Apr. 13, 2020), https://doi.org/10.1007/s40119-020-00179-2; Kumar Dharmarajan and Mathew Maurer, *Transthyretin Cardiac Amyloidoses in Older North Americans*, J. Am. Geriatric Society (Feb. 13, 2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3325376/.

39. Tafamidis treatment significantly reduced the decline in patients' functional capacity and quality of life compared to placebo. Given the progressive nature of the disease and the mechanism through which it acts, tafamidis is expected to have greater benefit when administered early in the disease course.

40. Tafamidis was well tolerated in the trial, with a safety profile comparable to placebo and a rate of permanent discontinuation due to adverse events similar to placebo.

41. Based on the results of ATTR-ACT, FDA designated tafamidis a Breakthrough Therapy—a designation reserved for medications "that are intended to treat a serious condition and [for which] preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s)."[4]

IV. FDA Approves Tafamidis as the Only Drug to Treat ATTR-CM

42. On May 3, 2019, the FDA approved tafamidis for the treatment of ATTR-CM to reduce cardiovascular mortality and cardiovascular-related hospitalization.

43. Tafamidis is the first and only medicine approved in the United States for treatment of ATTR-CM.

44. The director of the Division of Cardiovascular and Renal Drugs in the FDA's Center for Drug Evaluation and Research described tafamidis as "an important advancement in the treatment of the cardiomyopathy caused by transthyretin-mediated amyloidosis."[5]

[4] *See* FDA, *Breakthrough Therapy*, https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy (last visited June 14, 2020).

[5] FDA, *FDA Approves New Treatments for Heart Disease Caused by a Serious Rare Disease, Transthyretin Mediated Amyloidosis*, (May 6, 2019), https://www.fda.gov/news-events/press-announcements/fda-approves-new-treatments-heart-disease-caused-serious-rare-disease-transthyretin-mediated.

V. The Effect of the Medicare Benefit Design is to Hinder Access to Tafamidis for Middle-Income Americans

45. Medicare is a federal health insurance program that covers individuals age 65 and older, as well those under age 65 with certain disabilities or conditions. Congress enacted Medicare Part D in 2003. 42 U.S.C. § 1395w-101 *et seq.*; Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003). Through Part D, Congress made outpatient prescription coverage available to Medicare beneficiaries through private insurance plans, which are approved by Medicare. As of 2019, the Part D program covered 45 million Americans, representing approximately 70% of all Medicare beneficiaries.[6]

46. Congress included a cost-sharing feature in Medicare Part D plans. Under this cost-sharing scheme, the insured patient's out-of-pocket expense for medications is largely driven by the Medicare Part D benefit structure, which has several "phases":

a. ***Deductible.*** Beneficiaries are responsible for a deductible of $435 in 2020, meaning they pay 100% of the first $435 in eligible prescription costs.

b. ***Initial Coverage Phase.*** After beneficiaries have satisfied the deductible, they enter the initial coverage phase, in which they are responsible for a 25% coinsurance payment on any costs up to the initial coverage limit, which in 2020 is $4,020 for combined prescription medication spending by the beneficiary and the Part D plan.

c. ***The "Coverage Gap."*** Once combined prescription medication spending by the beneficiary and plan hits the initial coverage limit ($4,020 in 2020), beneficiaries enter a "coverage gap" phase, often referred to as the "donut hole." In the past,

[6] Juliette Cubanski *et al.*, *10 Things to Know about Medicare Part D Coverage and Costs in 2019*, Kaiser Family Foundation, (June 4, 2019), https://www.kff.org/medicare/issue-brief/10-things-to-know-about-medicare-part-d-coverage-and-costs-in-2019/.

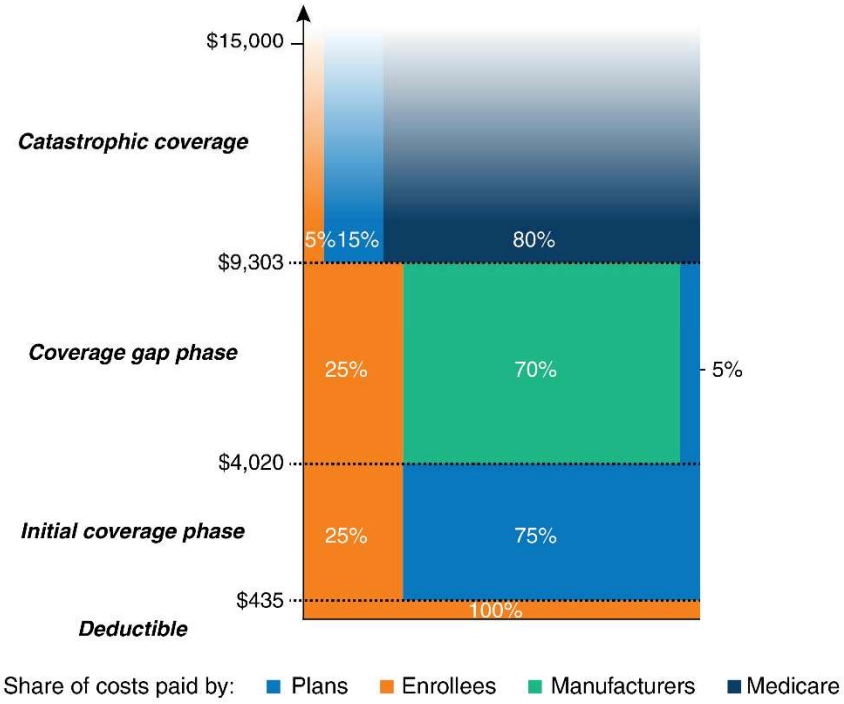
beneficiaries were responsible for almost all costs when they reached the "donut hole." In more recent years, as a result of changes brought about by the Affordable Care Act, the manufacturer has become responsible for the majority of medication costs during this phase. Still, in 2020, beneficiaries must cover 25% coinsurance payments in this "coverage gap" phase, until they have spent $2,652 out of pocket (inclusive of deductible and initial coverage coinsurance) and reach the catastrophic coverage threshold.[7]

d. ***Catastrophic Coverage.*** Beneficiaries enter the catastrophic coverage phase after their out-of-pocket spending, including during the "coverage gap" phase, reaches $2,652. After beneficiaries reach that threshold, they must continue to pay 5% of the cost of brand-name medications for the remainder of the coverage year. There is no financial cap on the amount that a patient can be required to pay for their medicine in a given year.

47. The below graphic details the standard Part D cost-sharing structure for brand-name medications as of 2020:

[7] This $2,652 figure (nearly 17% increase from 2019) represents the amount that a patient must personally pay out of pocket before reaching the catastrophic coverage threshold if the patient is using only branded medications. If a patient uses a mix of branded and generic medications, the patient's out-of-pocket cost before reaching the catastrophic coverage phase could vary. In addition, to the patient contribution, manufacturers contribute $3,698, for a total co-insurance of $6,350 that the plan does not cover. Juliette Cubanski, and Tricia Neuman, *How Will The Medicare Part D Benefit Change Under Current Law and Leading Proposals?*, Kaiser Family Foundation (Oct. 11, 2019), https://www.kff.org/medicare/issue-brief/how-will-the-medicare-part-d-benefit-change-under-current-law-and-leading-proposals/.

Medicare Part D Standard Benefit Cost Sharing Parameters in 2020



48. Depending on the enrollee's financial situation and the cost of the medicines they may need, Medicare Part D's cost-sharing structure can become financially onerous. In theory, cost sharing is intended to encourage patients to evaluate the need for discretionary care and to consider less expensive alternatives when available. But, in some cases, the Medicare Part D benefit design and patient cost-sharing obligations operate to put even medically necessary treatment out of reach for patients.

49. Congress made clear that it did not intend cost sharing to operate as a mechanism to ration access to essential medications (or to limit Part D benefits to only those wealthy enough to afford copay or coinsurance amounts). To mitigate against that result, Congress included in Medicare a Low Income Subsidy ("LIS") program that limits the impact of the Medicare Part D cost-sharing structure by providing additional coverage to patients falling below 150% of the Federal Poverty Level. To qualify for Medicare's LIS program, patients must earn less than

$19,140 annually. As a result of this income threshold, LIS assistance is unavailable to the majority of Medicare beneficiaries: of the approximately 45 million Part D enrollees in 2016, only an estimated 13 million (29%) qualified for the LIS program.[8]

50. Some patients for whom LIS is unavailable may obtain financial assistance through charities or from manufacturer-supported free drug programs, such as Pfizer's free drug program for tafamidis. If neither charitable assistance nor free medication is available, then a patient who is not wealthy but does not qualify for the LIS program may be forced to forgo treatment. Even where charitable assistance is obtained initially, a patient is not assured that it will continue to be available to help the patient with copays on a long-term basis.

51. Indeed, there is evidence that at least one quarter of new Medicare Part D prescriptions are abandoned if patients are asked to pay $50 or more (which is why Pfizer proposes a copay of $35 in its Proposed Programs).[9] The problem becomes more acute for beneficiaries with cancer or rare diseases, where the cost of developing treatments and a smaller patient population results in the manufacturer charging higher prices. Despite the severity of these diseases, the higher out-of-pocket costs of these medications cause many prescriptions to go unfilled and patients to go without treatment. In one study, 49% of cancer patients who had out-of-pocket costs over $2,000 did not fill their prescriptions. By comparison, the rate of unfilled prescriptions was only 10% amongst patients paying less than $10 for their prescriptions.[10]

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[8] Jack Hoadley et al., *Medicare Part D in 2016 and Trends over Time*, Kaiser Family Foundation, (Sept. 16, 2016), https://www.kff.org/report-section/medicare-part-d-in-2016-and-trends-over-time-section-4-the-low-income-subsidy-program/.

[9] *Drug pricing in America: A prescription for Change, Part II, Hearing Before the Senate Comm. on Finance*, 116th Cong 66 (2019) (prepared statement of Albert Bourla, DVM, Ph.D., Chief Executive Officer, Pfizer). https://www.finance.senate.gov/imo/media/doc/37143.pdf.

[10] Jalpa A. Doshi, et al., *Association of Patient Out-of-Pocket Costs with Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents,* J. of Clinical Oncology 476, (Feb. 10, 2018), https://ascopubs.org/doi/full/10.1200/JCO.2017.74.5091.

52. Tafamidis exemplifies the challenges to patient affordability resulting from Medicare's benefit design when it is applied to medicines that treat a rare disease and are, consequently, more expensive. Under the Medicare Part D benefit structure, a patient must pay approximately $13,000 in annual out-of-pocket expenditures for tafamidis, based on mandatory coinsurance through certain Part D phases (*i.e.,* deductible, initial benefit limit, coverage gap, and catastrophic) and certain formulary tiers (*e.g.,* specialty tier). This expense presents a prohibitive financial barrier for a significant proportion of Medicare patients.

53. Reduction in drug prices will not solve the affordability problem for innovative orphan drugs like tafamidis under Medicare Part D's benefit structure. That is because Medicare Part D front loads costs by requiring patients to pay at least $2,652 of their medicines' costs before they reach the catastrophic coverage phase of the benefit—an onerous threshold that prevents access to most innovative orphan drug treatments. Moreover, after a beneficiary hits the catastrophic coverage phase, Part D's lack of an out-of-pocket spending cap means patients are still responsible for significant co-insurance costs. Thus, even if tafamidis' price were cut in half, the $2,652 initial out-of-pocket costs to patients would not be reduced at all and the total cost to patients, approximately $8,000 annually, would remain prohibitive for most patients.

54. For many Part D enrollees, spending thousands of dollars in annual prescription expenses is beyond their means. Those patients will not be able to fill their prescription and, without assistance, will be forced to forgo the treatment.

55. The result is that, without assistance, many ATTR-CM patients will not be able to afford the Medications that can help extend their lives.

56. The Medicare Part D statute or regulations do not directly prohibit manufacturers or other entities from providing copay assistance to Medicare patients.

57. As discussed below, however, OIG has construed the AKS and BIS to categorically ban manufacturers, but not others, from offering copay assistance to Medicare patients under any circumstances. OIG's interpretation of those statutes also substantially restricts manufacturer support of independent charities that could provide such financial support. That construction improperly expands the prohibitions in the AKS and BIS, which are aimed at preventing fraud and bribery in medical decision-making. In so doing, OIG's position broadly blocks patients' access to Medicare coverage in a manner not contemplated by Congress when it established the Part D program.

VI. Pfizer's Proposed Copay Assistance Programs Would Allow Medicare Patients to Access these Breakthrough, Life-Extending Medications

58. Pfizer's Proposed Copay Assistance Programs would help ensure that financial obstacles do not prevent ATTR-CM patients, who have been appropriately prescribed tafamidis, from receiving the medication. More specifically, Pfizer proposes two possible solutions to facilitate patient access. Pfizer seeks to provide financial assistance to such patients to help them cover out-of-pocket expenses (copay and coinsurance) through the Direct Copay Assistance Program and/or the Independent Charity Program, which would mean funding an existing independent charity that would provide copay assistance to patients diagnosed with ATTR-CM who require financial support to access tafamidis (the only FDA-approved treatment for the disease state) as well as any other ancillary prescription drugs used to treat the symptoms of the disease and any potential side effects of treatment. Collectively, these are described as the "Proposed Copay Assistance Programs."

59. If Pfizer were to implement the Proposed Copay Assistance Programs, the out-of-pocket cost for eligible patients with Medicare insurance would be $35 per month for tafamidis.

60. The following paragraphs outline the proposed Programs that Pfizer has designed to help middle-income Medicare patients access the Medications. As discussed below, Pfizer submitted to OIG a request for an advisory opinion on the permissibility of the Proposed Copay Assistance Programs, as characterized herein. OIG refused to issue an advisory opinion on the Independent Charity Program and has informed Pfizer that it has reached an unfavorable opinion on the Direct Copay Assistance Program. At this juncture, Pfizer cannot proceed with either of the Proposed Copay Assistance Programs without facing a significant and imminent risk of enforcement action.

A. Direct Copay Assistance Program

61. The proposed Direct Copay Assistance Program would provide copay assistance directly to eligible Medicare Part D beneficiaries to help them pay the costs required to matriculate through the Part D deductible, initial coverage phase, and coverage gap and then to assist patients with affording the 5% coinsurance required during the catastrophic phase.

62. To be eligible to receive copay assistance under this Program, patients must: (1) be prescribed tafamidis for an on-label (approved) indication, that is, ATTR-CM; (2) be United States residents; and (3) meet program criteria for financial need tailored to address the burden otherwise faced by middle-income patients who are unable to access other available resources. Part D beneficiaries meeting those requirements who enroll in the program would pay a copay of $35 per month, after which Pfizer would pay 100% of each enrolled Medicare Part D beneficiary's monthly deductible or coinsurance amounts for tafamidis.

63. Pfizer would not advertise its Direct Copay Assistance Program or use it as a means to solicit new patients for tafamidis. Rather, the Direct Copay Assistance Program would offer copay assistance only after a physician diagnoses a patient with ATTR-CM and decides to prescribe tafamidis.

64. Nor would Pfizer routinely provide copay assistance to all patients prescribed tafamidis. Rather, patients requesting assistance through the Direct Copay Assistance Program would be individually evaluated, on a case-by-case income determination, based on a uniform measure of financial need, to ensure that patients meet the Program requirements. Pfizer would require patients to provide appropriate documentation to substantiate those financial need determinations.

65. The Direct Copay Assistance Program provides no financial incentive to physicians to favor tafamidis. Prescribers would exercise independent medical judgment on whether a patient should use tafamidis based on its efficacy and safety for treating ATTR-CM, after objective diagnosis of that condition and based on each patient's medical profile and treatment needs. Prescribers would receive no benefit from the program. Indeed, physicians currently prescribe tafamidis to ATTR-CM patients covered by Medicare in the absence of any direct copay assistance program, and they do so because tafamidis is the only approved medication for this deadly disease and because of its proven clinical benefits.

66. The Direct Copay Assistance Program has no more impact on a physician's prescribing decision for impacted patients than does the existence of the LIS program for indigent patients or the availability of existing financial assistance programs from Pfizer or any other third-party source.

67. The Direct Copay Assistance Program would put middle-income Medicare patients demonstrating financial need on similar footing as commercially insured patients suffering from ATTR-CM, who already benefit from Pfizer's copay assistance. The only difference between these patients is the type of insurance to which they have access.

68. Because no alternative pharmacologic therapies have been approved to treat ATTR-CM (and a dual organ transplant is both far more expensive and rarely a viable option), the proposed arrangement presents no risk of inappropriately steering ATTR-CM patients toward tafamidis or improperly inducing prescriptions for tafamidis.

69. In summary, the Direct Copay Assistance Program will enable patients to access the sole effective treatment for ATTR-CM and put middle-income patients on similar footing with wealthy patients who can afford the out-of-pocket costs, low-income patients who qualify for LIS subsidies, and commercially insured patients who have access to Pfizer's analogous patient assistance programs. The Program will advance Medicare's purpose and improve patient care, and does not constitute an illegal kickback, as discussed below.

B. Independent Charity Program

70. Pfizer's proposed Independent Charity Program would fund an existing independent charity to develop a copay assistance fund specifically for ATTR-CM patients.

71. The independent charity would provide copay assistance to patients diagnosed with ATTR-CM who require financial support to access tafamidis and any other prescription drugs used to treat the symptoms of the disease and any potential side effects of treatment. These other prescription drugs would include other manufacturers' products, and they would be ancillary to the treatment of the disease state itself.

72. Pfizer would communicate with the charity about the scope of the fund and funding needs, but the charity would retain independence to establish patient eligibility criteria, to ensure patients make a showing of financial need and have been appropriately prescribed tafamidis, and to determine how to allocate funds.

PFIZER'S PROPOSED COPAY ASSISTANCE PROGRAMS ARE LAWFUL AS A MATTER OF PROPER STATUTORY CONSTRUCTION

I. The Anti-Kickback Statute ("AKS") and Beneficiary Inducement Statute ("BIS")

A. The Anti-Kickback Statute ("AKS")

73. The AKS is a criminal statute originally enacted as part of the Social Security Amendments Act of 1972 to combat fraud and abuse in the Medicare and Medicaid programs.

74. The AKS prohibits any person from knowingly and willfully offering, paying, soliciting, or receiving "remuneration" (*i.e.*, a thing of value), directly or indirectly, in cash or in kind, "to induce" the purchase, prescription, or recommendation of items or services payable under a federal health care program. 42 U.S.C. § 1320a-7b(b)(2).

75. Conviction under the AKS can result in severe consequences for pharmaceutical manufacturers, executives and employees, including the imposition of criminal or civil penalties (including serving as the basis for liability under the False Claims Act), and/or administrative sanctions. *See* 42 U.S.C. § 1320a-7(b)(15). Most dire for a pharmaceutical company, conviction can serve as grounds to exclude the company and its products from reimbursement under federal health care programs, including Medicare and Medicaid. 42 U.S.C. § 1320-7(a) and (b). Due to the outsized role of federal health insurance in the health care sector, a pharmaceutical company cannot afford the risk of exclusion.

76. Because the literal language of the AKS could be read very broadly and the consequences of conviction are so severe, Congress has enacted various statutory exemptions for different types of conduct that it would not want to deter. 42 U.S.C. § 1320a-7b(b)(3). The statutory exceptions demonstrate that Congress intends for the AKS to apply only in circumstances where the remuneration is intended to improperly or corruptly influence the relevant individual's decision-making.

77. In addition, Congress ordered HHS to promulgate regulatory "safe harbors," which define certain types of payments and other arrangements that cannot be the basis for criminal or civil liability even if they arguably might violate the literal language of the AKS if read broadly.[11] 42 U.S.C. § 1320a-7b(b)(3)(E). OIG has adopted 28 safe harbors that are currently in effect.

B. The Benefit Inducement Statute ("BIS")

78. The BIS, enacted as part of HIPAA in 1996, prohibits any person, organization, or entity from "offer[ing] to or transfer[ing] remuneration to any individual eligible for [Medicare, Medicaid or certain other federally funded State health care programs] . . . that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part," under federal health care programs. 42 U.S.C. § 1320a-7a(a)(5). The BIS also carries significant civil monetary penalties. *Id.* § 1320a-7a(a).

C. The "Remuneration" Element

79. Not all monetary payments qualify as "remuneration" under the BIS or under the AKS's implementing regulations. Even though "remuneration" can include "anything of value," the BIS statute and AKS regulations create an exception for copay waivers (the "Copay Waiver Exception"). Under the BIS, waivers of coinsurance or deductibles are not "remuneration" if: (i) the waiver is not offered as part of any advertisement or solicitation; (ii) the person does not routinely waive coinsurance or deductible amounts; and (iii) the person waives the coinsurance

[11] The Senate Committee Report explained Congress' intent in creating regulatory "safe harbors" as follows: "It is the understanding of the Committee that the breadth of [the] statutory language has created uncertainty among health care providers as to which commercial arrangements are legitimate, and which are proscribed. The Committee bill therefore directs the Secretary, in consultation with the Attorney General, to promulgate regulations specifying payment practices that will not be subject to criminal prosecution ... and that will not provide a basis for exclusion from participation in Medicare or the State health care programs." S. Rep. No. 109, 100th Cong., 1st Sess. 14 (1987), reprinted in 1987 U.S.C.C.A.N. News 682, 707.

and deductible amounts after determining in good faith that the individual is in financial need or fails to collect coinsurance or deductible amounts after making reasonable collection efforts. 42 U.S.C. § 1320a-7a(i)(6)(A). The regulations implementing the AKS create a similar Copay Waiver Exception to the definition of "remuneration." 42 C.F.R. § 1003.110.

80. In addition, the BIS creates an Access to Care Exception, which excludes from the statutory definition of "remuneration" arrangements that "promote[] access to care" and pose a low risk of harm to patients and federal health care programs. 42 U.S.C. § 1320a–7a(6)(D); 81 Fed. Reg. 88,368, 88,393 (Dec. 7, 2016) (regulations implementing Access to Care Exception).

81. According to OIG's regulations, an arrangement will pose a low risk of harm under the Access to Care Exception if it is "(1) . . . unlikely to interfere with, or skew, clinical decision making; (2) … unlikely to increase costs to federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (3) [does] not raise patient safety or quality-of-care concerns." 81 Fed. Reg. 88,368, 88,396 (Dec. 7, 2016); 42 C.F.R. § 1003.110 (2017).

82. Through these regulations, OIG has acknowledged that not all programs that eliminate financial obstacles that might prevent a patient from filling a prescription present a risk of over or inappropriate utilization.

83. OIG has, however, prevented individuals or companies from independently taking advantage of the statutory exception, by requiring them first to satisfy OIG that the exception is warranted. By regulation, OIG places the burden on "anyone asserting this exception . . . of presenting sufficient facts and analysis" to prove to OIG in advance that the particular arrangement promotes access to care and poses no more than a low risk of harm to patients or federal health care programs. 81 Fed. Reg. 88,368, 88,391 (Dec. 7, 2016).

D. **The "Inducement" Element**

84. A payment only violates the AKS or BIS if it is provided "knowingly and willfully . . . *to induce*" the purchase, prescription, or recommendation of items or services payable under a federal health care program.

85. In order to satisfy the inducement element of the AKS and BIS, the government must show that the defendant paid remuneration in an "attempt to gain influence over the reason or judgment of that person," where "that person" refers to the individual who received remuneration under the preceding inquiry. *United States v. Krikheli*, 461 F. App'x 7, 10–11 (2d Cir. 2012).

86. The requisite influence must be "improper," *see, e.g.*, *United States v. TEVA Pharm. USA, Inc.*, No. 13 CIV. 3702 (CM), 2016 WL 750720, at *17 (S.D.N.Y. Feb. 22, 2016); *Guilfoile v. Shields*, 913 F.3d 178, 192–93 (1st Cir. 2019), and the accompanying remuneration must be "offered or paid as a *quid pro quo*," *Krikheli*, 461 F. App'x at 10–11. "[T]he government [i]s required to prove that any payments . . . were made to induce referrals in a *quid pro quo* transaction." *Id.*

87. This requirement that the influence be "improper" or "corrupt," *i.e.*, in the nature of a "*quid pro quo*," is consistent with the Supreme Court's recognition that "kickback" has an established, circumscribed meaning under federal statutes, such as 41 U.S.C. § 8701(2), which defines "kickback" as a thing of value given "*for the purpose of improperly obtaining* or rewarding favorable treatment." *Skilling v. United States*, 561 U.S. 358, 412-13 (2010) (emphasis added) (citing also 18 U.S.C. § 666(a)(2) ("*corruptly* gives … anything of value … with intent to influence or reward"), and 18 U.S.C. § 201(b) (same)).

II. The Proposed Copay Assistance Programs Do Not Violate the AKS or BIS

88. Pharmaceutical manufacturer copays to federal health insurance beneficiaries are lawful under the AKS and BIS when, as in the case of tafamidis, the manufacturer does not knowingly and willfully intend for those copays to improperly or corruptly influence the prescribing or purchase of its product. Here, the proposed Programs do not meet either the remuneration or inducement elements of the AKS and BIS.

A. The Proposed Copay Assistance Programs Do Not Involve Prohibited Remuneration

i. The Copay Waivers Here Are Specifically Exempted from the Definition of "Remuneration"

89. The financial assistance to be provided under the Proposed Copay Assistance Programs meets each of the three requirements for the Copay Waiver Exception to the BIS and AKS implementing regulations. 42 U.S.C. § 1320a-7a(i)(6)(A) (BIS); 42 C.F.R. § 1003.110 (AKS implementing regulations). It would not be offered as part of any advertisement to solicit prescriptions for tafamidis; rather, it would be offered only to patients diagnosed with ATTR-CM who have already been prescribed tafamidis by their physician. Moreover, the waivers would not be "routine," as they instead would be granted on a case-by-case basis upon a documented demonstration of financial need based on objective criteria.

90. Additionally, the proposed Programs meet the Access-to-Care Exception because they increase access to necessary medical care and pose a low risk of harm to federal health care programs. 42 C.F.R. § 1003.110 (definition of "remuneration"); 81 Fed. Reg. 88,368, 88,393 (Dec. 7, 2016):

a. *The Proposed Copay Assistance Programs Do Not Interfere with Clinical Decision-Making*. Tafamidis is an FDA-designated "breakthrough therapy," the only FDA-approved medication for treatment of ATTR-CM, and the only treatment proven to reduce

mortality and slow decline in function and quality of life for patients with this deadly disease. As noted above, there are no realistic alternative treatments for the overwhelming majority of Medicare patients suffering from ATTR-CM and any copay assistance would be available only *after* the objective diagnostic and prescribing decisions of the patient's treating physician. Under those circumstances, copay assistance would not improperly alter clinical decision-making.

b. *The Programs Promote Appropriate Utilization, Not Overutilization*. As discussed above, only patients diagnosed with ATTR-CM who are prescribed tafamidis on-label by their physician and who have demonstrated financial need will be eligible for copay assistance. Thus, the effect of the Proposed Copay Assistance Programs would not be to induce unwarranted prescriptions, but to help ensure that appropriate patients have access to therapy regardless of their ability to pay. The lack of alternatives to tafamidis also eliminates the concern that patients could be locked into a particular product because of financial incentives. Any additional expenditure required for tafamidis would be appropriate and necessary to allow patients suffering from a debilitating and fatal condition to benefit from a breakthrough treatment that can extend life, as evidenced by Medicare's willingness to pay its share of tafamidis' cost for patients covered by LIS or beneficiaries who are able to afford their coinsurance obligations from their personal resources or other third-party sources.

c. *The Programs Promote Patient Safety and Quality of Care*. For most patients with ATTR-CM, tafamidis will be the best and only available treatment. The fact that the Programs would increase access to tafamidis for appropriate patients would improve the quality of patient care and patient outcomes. Copay support in this context—whether from an independent charity or directly from Pfizer—is designed to allow doctors to make treatment decisions based on their

patients' best clinical interest, ensuring that financial need does not impede patient access to these life-changing Medications.

ii. The Proposed Independent Charity Program, by Involving an Independent Charitable Organization, Takes the Assistance Even Further from Remuneration

91. The proposed Independent Charity Program is even further outside the statutory prohibitions of the AKS and BIS, because the ostensible remuneration would not be provided ***to*** the person who would supposedly be induced.

92. The AKS and the BIS only encompass transfers of remuneration to a person in order to corruptly induce or influence ***that person's*** decisions about the provision of medical services funded under a federal health care program. *See* 42 U.S.C. § 1320a-7b(b)(2)(B); 42 U.S.C. § 1320a-7a(a)(5). While the connection between the remuneration and the induced individual can be "direct[] or indirect[]," 42 U.S.C. § 1320a-7b(b), there still must be a causal chain connecting the two.

93. As OIG has long acknowledged in its guidance, making charitable donations to an independent organization that facilitates access to medication does not qualify as prohibited remuneration provided—even indirectly—"to" the person to be induced as long as the charity remains independent and the donations are not intended to improperly induce the independent organization to recommend or arrange for the purchase of the manufacturer donor's federally reimbursable items. Precisely because the "bona fide charitable assistance programs" are "independent," the manufacturers that contribute to the independent charity are not providing prohibited "remuneration" to any specific patient.

94. Nor does the fact that tafamidis is the only FDA-approved treatment option for ATTR-CM change the analysis under the AKS' and BIS' remuneration prong, which hinges on the bona fide independence of the charity, not the breadth of its charitable goals. Through guidance

issued in both 2005 (the "2005 Guidance") and 2014 (the "2014 Guidance"), OIG has acknowledged the fact that "a disease fund includes only one drug or drugs made by one manufacturer would not, standing alone, be determinative of an anti-kickback statute violation." 70 Fed. Reg. 70,623-03, 70,627 n.19 (Nov. 22, 2005); 79 Fed. Reg. 31,120, 31,122 (May 30, 2014). Once again, the independence of the charity means that the manufacturer has not provided "remuneration" to the patient, even when a charitable fund, by its own design, supports only one approved product.

95. OIG's 2005 Guidance suggests that certain communications with independent charities can undermine their independence and turn them into a "conduit" for manufacturers to provide copay support to patients. 70 Fed. Reg. 70,623, 70,626-27 (Nov. 22, 2005). However, merely communicating with a charity about the levels of funding or other means of making the donation more effective does not eliminate that independence and transform those donations into remuneration.

B. The Proposed Copay Assistance Programs Are Not Intended to Improperly Induce Prescriptions for Tafamidis

96. In the circumstances of the Proposed Copay Assistance Programs, patient assistance would not "improperly" or "corruptly" influence the "reason or judgment" of a patient to fill a prescription for tafamidis.

97. Under the Proposed Copay Assistance Programs, any offer of copay assistance will occur only ***after*** a physician has diagnosed a patient with ATTR-CM on the basis of objective criteria and prescribed tafamidis. Moreover, the fatal nature of the disease, and the absence of alternative therapies, obviates concerns for over- or inappropriate utilization. In these circumstances, the Proposed Copay Assistance Programs will facilitate access to tafamidis, remove

barriers to therapy, and encourage adherence to science-based treatment decisions. The Programs will not improperly induce or influence either the physician's or patient's decision-making.

98. Patients who are diagnosed with ATTR-CM have only three options: (1) they can live with a progressive, debilitating disease that results in death, typically within 2 to 3.5 years; (2) they can see if they are medically eligible for a more expensive, more invasive, and more dangerous dual heart and liver transplant; or (3) they can take a prescribed course of tafamidis. Faced with those choices, the notion that the Proposed Copay Assistance Programs induce—much less *improperly* induce—a patient to choose the third option is unsupportable.

IN LIGHT OF OIG'S INTERPRETATION OF ANTI-FRAUD STATUTES, PFIZER CANNOT IMPLEMENT THE PROPOSED PROGRAMS WITHOUT SIGNIFICANT RISK OF INCURRING AN ENFORCEMENT ACTION

99. Notwithstanding the clear social and medical benefits of Pfizer's Proposed Copay Assistance Programs, which would allow middle-income Part D beneficiaries to access tafamidis in the same way their wealthier and poorer fellow Medicare beneficiaries do, OIG's overly broad interpretation of the AKS and BIS prevents Pfizer from doing so. OIG's interpretation is wrong, and Pfizer's Proposed Copay Assistance Programs are lawful as a matter of proper statutory construction.

100. Congress enacted the AKS and BIS to combat health care fraud. OIG, however, has adopted the view that the AKS and the BIS categorically prohibit pharmaceutical manufacturers from providing direct copay assistance to Medicare patients (and other federal health care beneficiaries), irrespective of whether such assistance would provide access to critically needed medications, rather than improperly corrupt medical decision-making. This view is clear from OIG's guidance documents and enforcement history regarding pharmaceutical copay assistance to Medicare patients, and from OIG's rejection of Pfizer's request for an advisory

opinion supporting the Programs. OIG has further issued guidance that imposes severe limitations on pharmaceutical manufacturers' funding of, and communications with, independent charities that provide financial assistance to Medicare patients. The combination of OIG's actions effectively prevents Pfizer from implementing its proposed Programs, even though they do not violate federal kickback laws.

I. OIG's Rejection of Pfizer's Request for an Advisory Opinion Supporting Direct Copay Assistance for Tafamidis

101. Because many entities could reasonably fear that their common, lawful business activities might arguably fall within the literal language of the AKS and BIS, even though they raise no genuine concern of fraud, Congress enacted a process by which an entity could seek an advisory opinion that its proposed conduct would not violate the statute. 42 U.S.C. § 1320a-7d(b). The entity could also seek an advisory opinion that the proposed activity does not "constitute[] grounds for the imposition of a sanction" of exclusion. 42 U.S.C. § 1320a-7d(b)(2)(E). Congress went so far as to provide that the OIG's opinion would be binding on both OIG and the requestor. 42 U.S.C. § 1320a-7d(b)(4)(A).

102. This highly unusual statutory procedure reflects Congress's desire not to chill socially beneficial behavior.

103. On June 27, 2019, Pfizer submitted to OIG a request for an advisory opinion on the legality of both the Independent Charity Program and the Direct Copay Assistance Program.

104. On August 2, 2019, OIG rejected that request, indicating that it was "not able to issue an advisory opinion" as to the Independent Charity Program "because 'the same or substantially the same course of action is under investigation, or has been the subject of a[n]

[enforcement] proceeding involving [HHS] or another governmental agency.'"[12] On August 26, 2019, after conferring with OIG, Pfizer resubmitted this request, limiting it to the Direct Copay Assistance Program and excluding the Independent Charity Program.

105. On December 9, 2019, OIG orally informed Pfizer that it had reached an unfavorable opinion on the Direct Copay Assistance Program because the Program would implicate the AKS and BIS, and that OIG would issue an opinion to that effect if Pfizer did not voluntarily withdraw the request.[13]

106. In response to OIG's December 9, 2019 decision, Pfizer sought a further meeting with OIG to explain why Pfizer believed its Direct Copay Assistance Program did not violate the AKS or BIS, and, furthermore, why there was little risk of fraud or abuse given the particular characteristics of tafamidis as the sole FDA-approved medication to treat ATTR-CM.

107. During a teleconference with OIG on March 30, 2020, and in a follow-up written letter, Pfizer further clarified the steps it would take to ensure that the Direct Copay Assistance Program would be limited to eligible beneficiaries of federal health care insurance who had been objectively diagnosed with ATTR-CM, had been prescribed tafamidis by their physician, and were only unable to access their medication due to financial need.

108. Nonetheless, on May 26, 2020, OIG informed Pfizer that its position was unchanged and it would issue an unfavorable advisory opinion on the Direct Copay Assistance Program if Pfizer did not voluntarily withdraw the request. OIG declined to provide Pfizer any

[12] Based on discussions with OIG, it is Pfizer's understanding that the conduct under investigation was not Pfizer's donations to independent charities but the conduct of other companies.

[13] This is OIG's common practice when it has reached an unfavorable decision on a request for advisory opinion. *See* HHS OIG, *Advisory Opinion FAQs* (stating that OIG "generally find[s] that informal consultation with the requesting parties helps us with our review and analysis of requests" and that it "will initiate discussions with a requesting party's designated contact person at the point at which we would find such discussions useful," but also noting that "regulations permit the requesting party to withdraw its request at any time before the opinion is issued"), https://oig.hhs.gov/faqs/advisory-opinions-faq.asp (last visited June 25, 2020).

feedback regarding how the Direct Copay Program could be modified such that OIG would give a favorable opinion. Pfizer accordingly has no further administrative avenues of relief to pursue with OIG.

109. OIG's long-standing guidance, and its decision to reject Pfizer's request for a supportive advisory opinion on the proposed Programs, leave Pfizer unable to engage in its desired conduct and with no avenues for further agency review. Absent this Court's intervention, Pfizer's only options are to comply with OIG's current interpretation of the AKS and BIS in its guidance, or else, go forward subject to the significant and credible threat of enforcement. If the Court declares, however, that the proposed Programs do not constitute prohibited "remuneration" or result in any improper "inducement," and thus do not violate either the AKS or BIS, then Pfizer would be free to initiate the Programs.

II. OIG Guidance Improperly Restricts Copay Assistance and Interactions with Independent Charity Programs that Benefit Medicare Patients

110. OIG has issued a series of guidance documents that establish its position that direct copay assistance is prohibited by the AKS and BIS and establishing severe restrictions on pharmaceutical manufacturers' ability to fund and interact with independent charities that provide financial support to federal health care beneficiaries. [14]

A. OIG's Limits on Direct Copay Assistance to Federal Health-Care Beneficiaries

111. In its 2005 Guidance, OIG stated its position that cost-sharing subsidies provided by "pharmaceutical manufacturer" patient assistance programs to Medicare Part D patients to help with out-of-pocket costs "would implicate the anti-kickback statute and pose a substantial risk of program and patient fraud and abuse" under Medicare Part D. 70 Fed. Reg. 70,623-03, at 70,625

[14] The Health Care Fraud and Abuse Control Program, established by HIPAA, authorizes OIG to provide guidance to prevent fraud and abuse. As part of this mandate, OIG issues Special Advisory Bulletins about industry practices or arrangements that potentially implicate the fraud and abuse authorities subject to enforcement by OIG.

(Nov. 22, 2005). Even more categorically, OIG stated that manufacturer "subsidies [for their Part D drugs] would be squarely prohibited by the statute, because the manufacturer would be giving something of value (*i.e.*, the subsidy) to beneficiaries to use its product." *Id.*

112. OIG has further stated its view that manufacturer copay assistance programs "present all of the usual risks of fraud and abuse associated with kickbacks, including steering beneficiaries to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing beneficiaries' incentives to locate and use less expensive, equally effective drugs." *Id.* On those bases, OIG concluded that such programs could cause "[i]ncreased costs to the [Medicare] program" by inducing overutilization and could cause "[b]eneficiary steering and anti-competitive effects" by "locking beneficiaries into the manufacturer's product, even if there are other equally effective, less costly alternatives (and even if the patient's physician would otherwise prescribe one of these alternatives)." *Id.* at 70,625-26.

113. OIG's 2014 "Special Advisory Bulletin"[15] further advised pharmaceutical manufacturers that "copayment coupons" that "reduce or eliminate the cost of [patients'] out-of-pocket copayments . . . constitute remuneration offered to consumers to induce the purchase of specific items" and therefore, OIG found they implicate the AKS. OIG warned that, "[p]harmaceutical manufacturers that offer copay coupons may be subject to sanctions" if they fail to ensure that the coupons are not used by Part D beneficiaries.[16] That warning was categorical without any indication that OIG would *ever* view copay coupons as permissible for federally

[15] HHS OIG, Special Advisory Bulletin – Pharmaceutical Manufacturer Copayment Coupons, (Sept. 2014), https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf. The Health Care Fraud and Abuse Control Program, established by HIPAA, authorizes OIG to provide guidance to prevent fraud and abuse. As part of this mandate, OIG issues Special Advisory Bulletins about industry practices or arrangements that potentially implicate the fraud and abuse authorities subject to enforcement by OIG.

[16] *Id.* at 3.

insured patients.[17] Since that time, OIG and DOJ aggressively have enforced a policy of prohibiting pharmaceutical manufacturers (but not others) from providing any form of copay assistance to federal health care beneficiaries.

114. As OIG has acknowledged, Congress's concern in adopting the AKS and BIS was with providing financial advantages that might steer providers or patients to a particular drug over competitors, or reduce incentives to locate and use less expensive, equally effective drugs, thus reducing the effectiveness or increasing the costs of Medicare. 70 Fed. Reg. 70,623-03, at 70,625 (Nov. 22, 2005). Any analysis of whether a particular program is permissible should, therefore, turn on those criteria. Yet, by imposing a blanket prohibition on manufacturer-funded copay assistance, OIG has drawn an arbitrary line that hinges solely on *who* is providing the financial assistance. Meanwhile, under OIG's guidance, if the person or entity providing financial assistance were a wealthy relative or charity, the subsidy is acceptable. Though OIG has not articulated its reasoning, its endorsement of third-party charitable assistance to Medicare patients makes evident that OIG does not require patients to personally pay the out-of-pocket costs for their prescribed medications. OIG's categorical interpretation of the law barring manufacturers from providing the same assistance to patients fails to recognize the possibility that, in some circumstances—such as that presented by the proposed Programs—a manufacturer's assistance might *improve* health care by allowing patients to access needed medicines that they simply cannot afford, without posing the risks the AKS and BIS were designed to address. In such circumstances, a manufacturer may provide financial assistance to enable Medicare patient access to medicines without falling within the scope of the AKS's and BIS's statutory prohibition.

[17] *Id*.

B. OIG's Restrictions on Pharmaceutical Manufacturer's Interactions with Independent Charities

115. As an alternative to direct copay assistance, OIG has recommended in guidance that manufacturers contribute to *independent* charity patient assistance programs as an avenue to assist financially needy Medicare Part D patients with their out-of-pocket costs. *See* 70 Fed. Reg. 70,623, 70,626-27 (Nov. 22, 2005) OIG noted that "[l]ong-standing OIG guidance makes clear that pharmaceutical manufacturers can effectively contribute to the pharmaceutical safety net by making cash donations to independent, bona fide charitable assistance programs." *Id.* at 70,626.

116. However, OIG has sought to limit even that avenue for assistance. The OIG guidance imposes severe restrictions on a pharmaceutical manufacturer's communications with and donations to independent charities that impede the manufacturer's ability to bestow a meaningful and effective gift by, for example, ensuring the charity has sufficient funds to cover all patients who require assistance accessing treatment or medication. In particular, OIG's 2005 Guidance provides that, "[p]harmaceutical manufacturers should not influence, directly or indirectly, the identification of disease or illness categories, and pharmaceutical manufacturers should limit their earmarked donations . . . that define categories in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products." *Id.* Any discussions between a manufacturer and an independent charity regarding funding levels or patient needs could be considered "attempting to influence," thus violating OIG's broadly worded guidance and creating grounds for the government to assert an AKS or BIS violation. As a consequence, independent charities often structure their funds to cover many products for a number of related disease states, and there is no guarantee that the funds go to patients in need for a particular disease state.

117. Moreover, OIG's 2005 Guidance stated that OIG would look with suspicion on charities focused on a narrow disease category with only one treatment. *Id.* at 70,627. In its 2014 Guidance, OIG further tightened the 2005 Guidance and asserted that charities "with narrowly defined disease funds" may be "subject to scrutiny" if the disease funds "result in funding exclusively or primarily the products of donors or if other facts and circumstances suggest that the disease fund is operated to induce the purchase of donors' products." 79 Fed. Reg. 31,120, 31,121 (May 30, 2014).

118. Following its 2014 Guidance, OIG issued a series of advisory opinions that imposed new conditions on charities that had previously received favorable advisory opinions, requiring the charities to certify that they would not provide help to patients through: (1) single disease funds; or (2) single treatment funds.[18]

119. Both the 2005 and 2014 Guidance acknowledged that, in "rare circumstances," a disease may have only one effective treatment and therefore a disease fund could, in theory, permissibly cover only one manufacturer's product." 70 Fed. Reg. at 70,627 n.19; 79 Fed. Reg. at 31,122. OIG explained, in those "unusual circumstances," the fact that "a disease fund includes only one drug or drugs made by one manufacturer would not, standing alone, be determinative of an anti-kickback statute violation." 70 Fed. Reg. at 70,627 n.19; 79 Fed. Reg. at 31,122. OIG did not further define, however, the circumstances in which such a fund is permissible, presumably leaving entities to seek guidance through the advisory opinion process or to risk enforcement action.

[18] *See, e.g.*, Notice of Modification of OIG Advisory Opinion No. 02-1 (Mar. 03, 2017); Notice of Modification of OIG Advisory Opinion No. 10-07 (May 05, 2016); Notice of Modification of OIG Advisory Opinion No. 04-15 (Dec. 30, 2015).

120. The ambiguity in OIG's guidance on single drug funds makes any charitable copayment support by Pfizer for ATTR-CM patients virtually impossible without judicial clarification of Pfizer's legal rights. Under the government's current enforcement regime, which could result in considerable penalties, independent charities are reluctant to establish a fund for ATTR-CM patients because the Medications are the only FDA-approved drug to treat the condition. Under current OIG guidance, such a fund would be permissible if it also "provided support for other medical needs of patients with the disease," including all prescription medicines to treat symptoms of the disease and side effects of treatment.[19] Still, the practical reality is that OIG has never approved a so-called "single drug fund." Moreover, given that four charities have reached settlements with DOJ related to single drug funds in just the past three years, without assurance that they will not face prosecution, none presently is willing to risk running afoul of OIG's opaque interpretations by establishing a fund for ATTR-CM patients. Pfizer therefore can donate to independent charities that have established funds that cover a number of disease states collectively, including ATTR-CM, but there is no guarantee that these donations would go to ATTR-CM patients in need.

III. Pfizer Faces Imminent Risk of Government Enforcement If It Implements Its Proposed Copay Assistance Programs

121. Notwithstanding OIG's assertion that it would evaluate patient assistance arrangements on a case-by-case basis,[20] DOJ broadly has treated a company's failure to adhere strictly to OIG's guidance on copay and charitable assistance as evidence of intent to violate the AKS or BIS. This determination has serious implications for pharmaceutical manufacturers and

[19] *See, e.g.*, OIG Advisory Opinion No. 10-07 (May 5, 2016).

[20] OIG has stated that "a determination regarding whether a particular arrangement violates the anti-kickback statute requires a case-by-case evaluation of all the relevant facts and circumstances, including the intent of the parties." 70 Fed. Reg. 70,623-03, 70,625 (Nov. 22, 2005).

for patients who rely on financial support from such charitable programs, and it has effectively foreclosed manufacturers from providing direct copay assistance to federal health-care beneficiaries, including Medicare patients.

122. The consequences of an AKS or BIS conviction are Draconian, including the possibility of a pharmaceutical manufacturer's total exclusion from federal reimbursement for its medications. A violation of the AKS or BIS may also serve as a predicate for violation of the False Claims Act, which the government uses to assert a right to collect treble the value of the products implicated, in addition to millions of dollars in statutory penalties. Because of the dire consequences of False Claims Act, AKS, or BIS conviction, unless a pharmaceutical manufacturer can persuade the government not to pursue the matter, it almost always is forced to resolve investigations before they have had any opportunity to test the government's expansive reading of the AKS and BIS in court.

123. In fact, from December 2017 through January 2020, the government collected more than $840 million in settlements with eight pharmaceutical companies (including Pfizer) and $13 million in settlements with four independent charitable foundations, in order to resolve allegations of False Claims Act liability premised on AKS violations in connection with independent charities or direct patient assistance.[21] The government initiated these investigations on the premise that direct copay assistance violates the AKS, and that companies that fail to follow OIG guidance on donations to independent charity foundations are therefore presumptively attempting to pay for patients' copays in violation of the AKS.

[21] Depa't of Justice, U.S. Att'y Office, Dist. of Mass., *Fourth Foundation Resolves Allegations that it Conspired with Pharmaceutical Companies to Pay Kickbacks to Medicare Patients*, (Jan. 21, 2020), https://www.justice.gov/usao-ma/pr/fourth-foundation-resolves-allegations-it-conspired-pharmaceutical-companies-pay.

124. Although OIG has acknowledged the important role that independent charities play in the pharmaceutical payment system, OIG's enforcement posture severely constrains the ability of manufacturers to support those charitable programs to facilitate patients' access to novel treatments, much less to provide financial support directly. The threat of criminal prosecution and other severe penalties in conjunction with an aggressive enforcement posture creates untenable risk for companies to go forward with charitable support activities, even though the companies believe those activities are lawful under the AKS and BIS. The result of this legal uncertainty is reduced funding for and effectiveness of independent charities, which in turn, reduces the support for needy patients to receive prescribed treatments.

A. Pfizer Is at Heightened Risk of Enforcement Because Its Corporate Integrity Agreement Binds It to Follow OIG Guidance

125. On May 22, 2018, in resolution of an investigation of Pfizer's prior contributions to and interactions with independent charities, Pfizer and OIG entered into a Corporate Integrity Agreement ("CIA"), which set forth mutual obligations between Pfizer and OIG. Among other obligations, the CIA requires Pfizer to "comply with all guidance issued by OIG relating to the support and funding of patient assistance programs," including OIG's 2005 and 2014 Guidance.[22] As a result, if OIG's current position that the Proposed Copay Assistance Programs violate the AKS and BIS stands, Pfizer would also be precluded from implementing the Programs under the CIA.[23]

126. The CIA also imposes many restrictions on monetary donations by Pfizer to independent charities and on Pfizer's communications with those charities. For example, Pfizer

[22] HHS OIG, Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Pfizer Inc., § III(B)(b) (May 23, 2018), https://oig.hhs.gov/fraud/cia/agreements/Pfizer_Inc_05232018.pdf.

[23] The CIA obligates Pfizer to comply with OIG guidance, but does not waive Pfizer's statutory and constitutional rights to petition OIG or the Court for relief from policies that are outside OIG's authority.

may not influence the "identification, delineation, establishment, or modification of, or the parameters relating to" any independent charity's disease fund or its process or criteria for determining eligibility of patients who qualify for its assistance program, may not solicit or use any data or information from an independent charity to correlate the amount or frequency of its donations, and may not provide donations for a disease state fund that covers only a single product or that covers only Pfizer's products.

127. OIG has discretion to determine whether Pfizer has violated the terms of its CIA, and the potential consequences are severe. If OIG were to find that Pfizer violated the CIA, Pfizer could be subject to potentially massive financial penalties, which increase each day that OIG determines Pfizer to be in violation. Critically, if OIG determines that Pfizer has materially breached the CIA, Pfizer could be subject to exclusion from participation in federal health care programs, and "[t]he length of exclusion shall be in OIG's discretion, but not more than five years per material breach." Even a slight risk of these consequences is untenable for any company in the health care industry, let alone a global biopharmaceutical company.

B. OIG's Rejection of Pfizer's Request for A Favorable Advisory Opinion Regarding the Proposed Copay Assistance Programs Puts Pfizer at Heightened Risk of Enforcement

128. As detailed above, Pfizer has attempted to utilize OIG's advisory opinion process to secure approval of the proposed Programs, but to no avail: after a year-long process of engagement with OIG, the agency has refused to issue any opinion with respect to the Independent Charity Program and has informed Pfizer it has rejected the Direct Copay Assistance Program.

129. OIG's unfavorable decision on Pfizer's request for an advisory opinion exposes Pfizer to increased risk of criminal and civil enforcement action from the government if it were to implement the Programs.

130. Without an advisory opinion permitting Pfizer to proceed with the Proposed Copay Programs, Pfizer is bound by OIG's current interpretation of the AKS and BIS, as articulated in its guidance, and cannot proceed with the Programs without threat of enforcement and without potentially violating its CIA.

OIG'S CONSTRUCTION OF THE AKS OR BIS TO PROHIBIT THE PROPOSED COPAY ASSISTANCE PROGRAMS RAISES SERIOUS CONSTITUTIONAL CONCERNS

131. The Proposed Copay Assistance Programs are protected by the First Amendment. The proposed Independent Charity Program would include Pfizer's communications with the independent charity about its preferred charitable goals. An independent charity's communications regarding the creation of a single-drug fund for tafamidis as a way of, among other things, spurring increased charitable giving from Pfizer, is protected activity under the First Amendment.

132. The AKS and BIS already prohibit kickbacks, bribes, and other inducements. OIG's prohibitions on speech incident to charitable giving and solicitation are thus layered on top of these statutory prohibitions, ostensibly as further prophylaxis to prevent circumvention of the statutes. *See McCutcheon v. Fed. Election Comm'n*, 572 U.S. 185, 203 (2014). But as the Supreme Court has repeatedly explained, this "'prophylaxis-upon-prophylaxis approach' requires that we be particularly diligent in scrutinizing the law's fit," because it likely burdens far more speech than can be justified to achieve its legitimate goals. *Id.* at 221 (citation omitted). While OIG's speech restrictions may create clear "rules" about who can say what—and thus ease the burden of proving AKS and BIS violations, thereby also creating another tool for forcing pre-trial settlements—those ancillary benefits do not constitute a compelling government interest. Because that lone benefit is not compelling, no amount of tailoring will suffice and, as a result, the rules imposed by OIG's guidance in this area violate the First Amendment.

133. The speech restrictions are, in any event, overbroad. The communications Pfizer proposes here allow an independent charity to better assist patients and more efficiently meet patient needs. Particularly since ATTR-CM patients have no effective alternative to tafamidis, such communications do not pose a significant risk to any compelling government interest.

134. Notably, Pfizer's efforts to communicate with a charity in order to help that charity assist patients in overcoming access barriers and affording their medications is the same kind of speech that other organizations engage in; the Defendants may not constitutionally single out pharmaceutical manufacturers' speech for restriction.

135. Additionally, the government's interpretation of the AKS and BIS in a manner that significantly hinders access to life-changing medicine for patients with limited financial means, while covering costs for wealthier patients, raises serious equal protection concerns. The purpose of a public insurance program is to ensure that rich and poor alike have access to medical care. Given how the cost-sharing structure of Medicare Part D functions, any construction of the AKS and BIS to prohibit the Proposed Copay Assistance Programs would restrict patients' access to tafamidis solely on the basis of their economic status. In these circumstances, rationing Medicare Part D beneficiaries' access to tafamidis by prohibiting them from benefitting from Pfizer's Proposed Copay Assistance Programs would result in irrational discrimination against middle-income Americans. In the absence of copay assistance, two Medicare beneficiaries—each with the same medically certain diagnosis, each of whom could benefit equally from tafamidis—will have significantly different experiences based on nothing other than their independent financial resources. As a result, the government's actions cannot stand under the Fifth Amendment.

136. The AKS and BIS and the associated regulatory scheme should be construed to permit the Proposed Copay Assistance Programs and avoid these constitutional questions.

COUNT I

Pfizer Is Entitled to a Declaration That the Proposed Copay Assistance Programs Do Not Violate the AKS or BIS

28 U.S.C. § 2201

137. Pfizer incorporates and re-alleges Paragraphs 1–136 as if fully set forth herein.

138. The Declaratory Judgment Act provides that "[i]n a case of actual controversy within its jurisdiction, . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration." 28 U.S.C. § 2201(a).

139. The AKS and BIS do not prohibit the Proposed Copay Assistance Programs, at least because those programs would not satisfy the remuneration and/or inducement elements of those statutory schemes.

140. An actual controversy or a practicable issue exists between the parties, within the jurisdiction of this Court and involving the rights and liabilities of the parties under the Constitution and laws of the United States, which controversy may be determined by a judgment of this Court.

141. Pfizer is an interested party to the government's actions and is entitled to challenge those actions.

142. Pfizer has exhausted all of its available administrative remedies and/or pursuit of any further administrative remedies would be futile. Pfizer has no adequate remedy at law.

143. Pursuant to Fed. R. Civ. P. 57, the Court "may order a speedy hearing of a declaratory-judgment action." In consideration of the pressing and urgent need for early resolution of this case, Pfizer hereby respectfully requests entry of a judgment in its favor on an expedited basis as provided in Fed. R. Civ. P. 57.

COUNT II

Pfizer Is Entitled to a Declaration That The Application of OIG's Guidance To The Proposed Independent Charity Program Would Violate The First Amendment

28 U.S.C. § 2201

144. Pfizer incorporates and re-alleges Paragraphs 1–143 as if fully set forth herein.

145. The Declaratory Judgment Act provides that "[i]n a case of actual controversy within its jurisdiction, . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration." 28 U.S.C. § 2201(a).

146. If OIG prevented the Proposed Independent Charity Program, it would infringe on Pfizer's First Amendment right to engage in speech incident to charitable giving and would impose impermissible speaker-based restrictions on Pfizer as a pharmaceutical manufacturer.

147. An actual controversy or a practicable issue exists between the parties, within the jurisdiction of this Court and involving the rights and liabilities of the parties under the Constitution and laws of the United States, which controversy may be determined by a judgment of this Court.

148. Pfizer is an interested party to the government's actions and is entitled to challenge those actions.

149. Pfizer has exhausted all of its available administrative remedies and/or pursuit of any further administrative remedies would be futile. Pfizer has no adequate remedy at law.

150. Pursuant to Fed. R. Civ. P. 57, the Court "may order a speedy hearing of a declaratory-judgment action." In consideration of the pressing and urgent need for early resolution of this case, Pfizer hereby respectfully requests entry of a judgment in its favor on an expedited basis as provided in Fed. R. Civ. P. 57.

COUNT III

Pfizer Is Entitled to a Declaration That The Application of OIG's Guidance To The Proposed Copay Assistance Programs Would Violate The Fifth Amendment

28 U.S.C. § 2201

151. Pfizer incorporates and re-alleges Paragraphs 1–150 as if fully set forth herein.

152. The Declaratory Judgment Act provides that "[i]n a case of actual controversy within its jurisdiction, . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration." 28 U.S.C. § 2201(a).

153. If OIG prevented the Proposed Copay Assistance Programs, it would discriminate on the basis of wealth without being rationally related to a legitimate government interest.

154. An actual controversy or a practicable issue exists between the parties, within the jurisdiction of this Court and involving the rights and liabilities of the parties under the Constitution and laws of the United States, which controversy may be determined by a judgment of this Court.

155. Pfizer is an interested party to the government's actions and is entitled to challenge those actions.

156. Pfizer has exhausted all of its available administrative remedies and/or pursuit of any further administrative remedies would be futile. Pfizer has no adequate remedy at law.

157. Pursuant to Fed. R. Civ. P. 57, the Court "may order a speedy hearing of a declaratory-judgment action." In consideration of the pressing and urgent need for early resolution of this case, Pfizer hereby respectfully requests entry of a judgment in its favor on an expedited basis as provided in Fed. R. Civ. P. 5.

COUNT IV

The Government's Actions Preventing Pfizer's Proposed Copay Assistance Programs Are Not in Accordance with Law and Contrary to Constitutional Rights under the Administrative Procedure Act

5 U.S.C. § 702

158. Pfizer incorporates and re-alleges Paragraphs 1–157 as if fully set forth herein.

159. The Administrative Procedure Act allows a person suffering a wrong or adversely affected by an agency action to receive judicial review of the agency's action. 5 U.S.C § 702. The reviewing court must set aside an agency's action that is "not in accordance with law" or "contrary to constitutional right." 5 U.S.C. § 706(2)(A) & (B).

160. OIG has engaged in series of actions that establish its position that it is illegal under the AKS and the BIS for Pfizer to implement its proposed Programs to assist ATTR-CM patients through (1) its 2005 and 2014 guidance; (2) its enforcement history; and (3) its refusal to grant Pfizer a favorable advisory opinion.

161. The AKS and BIS do not prohibit the Proposed Copay Assistance Programs because those programs do not meet the remuneration or inducement elements of those statutory schemes. The government's restrictions on pharmaceutical copay assistance generally, and its refusal to provide an advisory opinion affirming that the proposed Programs are not grounds for sanctions under the AKS or BIS, are therefore not in accordance with the law.

162. The government's actions infringe on Pfizer's First Amendment right to engage in speech incident to charitable giving and impose impermissible speaker-based restrictions on Pfizer as a pharmaceutical manufacturer. The government's actions are therefore contrary to a constitutional right.

163. The government's actions discriminate on the basis of wealth without being rationally related to a legitimate government interest. The government's actions are therefore contrary to a constitutional right.

164. In combination with its other actions, OIG's determination that the Proposed Copay Assistance Programs implicate the AKS and BIS is final agency action that prevents Pfizer from lawfully engaging in the Proposed Copay Assistance Programs.

165. Pfizer has exhausted all of its available administrative remedies and/or pursuit of any further administrative remedies would be futile.

166. Pfizer is entitled to challenge the government's actions. 5 U.S.C. §§ 701-706.

167. Pfizer has no adequate remedy at law.

168. Accordingly, Pfizer seeks a judgment setting aside OIG's determination that the Proposed Copay Assistance Programs implicate the AKS or BIS.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays that this Court:

169. Declare that the Proposed Copay Assistance Programs do not violate the AKS or BIS;

170. Declare that the application of OIG's Guidance to the Proposed Copay Assistance Programs would violate the First Amendment to the U.S. Constitution;

171. Declare that the application of OIG's Guidance to the Proposed Copay Assistance Programs would violate the Fifth Amendment to the U.S. Constitution;

172. Set aside OIG's determination that the Proposed Copay Assistance Programs implicate the AKS and BIS as not in accordance with law and contrary to a constitutional right;

173. Award Plaintiff such costs and reasonable attorney's fees to which it might be entitled by law; and

174. Award such other relief as this Court may deem just and proper.

Dated: June 26, 2020

Respectfully submitted,

/s/ Joan McPhee

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